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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/925,990	08/09/2001	Charles Joel Arntzen	P00245USG	5525

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DES MOINES, IA 50309-2721

EXAMINER	
ZEMAN, ROBERT A	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 06/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/925,990	ARNTZEN ET AL.	
	Examiner	Art Unit	
	Robert A. Zeman	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 March 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *73-79* is/are pending in the application.

4a) Of the above claim(s) *76-78* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *73-75 and 79* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *73-79* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The amendment and response filed on 3-1-2004 is acknowledged. Claims 73-75 have been amended. Claim 79 has been added. Claims 73-79 are pending. Claims 76-78 remain withdrawn from consideration. Claims 73-75 and 79 are currently under examination.

Information Disclosure Statement

With regard to the Information Disclosure Statement filed on 10-4-2001 (Paper No. 2), it should be noted that none of the previously non-considered references have become available. Said references will be considered when they become available.

Objections Withdrawn

Oath/Declaration

The objection to the he oath or declaration is defective is withdrawn in light of the unavailability or non-cooperation of Inventor Arntzen.

Claim Objections

The objection to claims 74 and 75 for reciting the confusing phrases "said plant is tomato" and "said plant is potato" is withdrawn in light of the amendment thereto.

Claim Rejections Withdrawn

Double Patenting

The rejection of claims 73-75 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 9-11 of U.S. Patent No. 6,034,298 is withdrawn in light of the terminal disclaimer filed on 3-1-2004

The provisional rejection of claims 73-75 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 48-51 and 56 of copending Application No. 09/918,937 is withdrawn in light of the terminal disclaimer filed on 3-1-2004.

The provisional rejection of claim 73 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 73 of copending Application No. 09/816,846 is withdrawn in light of the terminal disclaimer filed on 3-1-2004.

Claim Rejections Maintained

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The rejection of claim 73 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2-5 of U.S. Patent No. 5,612,487 is maintained for reasons of record. Although the conflicting claims are not identical, they are not patentably distinct from each other because the methods claimed in U.S. Patent No. 5,612,487 for the production of a hepatitis B viral surface antigen in transgenic plants would render the claimed invention of the instant application obvious since they both recite the same goals and the same basic method steps. Applicant states in his response that a terminal disclaimer was filed in order to obviate the instant rejection. To date, said terminal disclaimer has not been received.

35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 73-74 and 79 are rejected under 35 U.S.C. 102(b) as anticipated by Goodman et al. (WO 87/00865 – IDS-2) for the reasons set forth in the previous Office action in the rejection of claims 73-74.

The instant claims are drawn to a method of producing a vaccine comprising constructing a plasmid vector or DNA fragment comprising a DNA sequence encoding a viral antigen coupled to a plant functional promoter, transferring said vector or DNA fragment into a plant cell, regenerating a transgenic plant from said plant cell, obtaining the expressed viral antigen from a harvested portion of said transgenic plant and purifying said antigen. Said transgenic plant can be a tomato plant.

Applicant argues:

1. The amended claims recite the limitation "harvesting a portion of said regenerated transgenic plant, said portion containing said expressed immunogenic viral antigen, wherein said expressed antigen stimulates an immune response". Said limitation makes the instant claims distinguishable from the cited art since Goodman merely discloses that their proteins be "physiologically active".
2. Many protein antigens are not intrinsically immunogenic, particularly as a vaccine.
3. A protein antigen is not necessarily immunogenic unless an immunogenic region is present and accessible to the antibody-forming mechanism.
4. Goodman discloses constructs encoding physiologically active proteins such as interferon but do not disclose physiologically active peptides that have any immunoregulatory functions.

5. Goodman discloses the production of primarily digestive enzymes that may or may not have immunogenic activity.

6. As illustrated by the reference by Service, the state of the art at the time of the Goodman reference was such that when an antigen in a plant was consumed by an animal it was unknown whether it would be digested or induce an immune response.

7. The art recognized problems associated with oral vaccines are not taken into account by Goodman.

Applicant's arguments have been fully considered and deemed non-persuasive.

With regard to Points 1 and 2, since Goodman et al. disclose the expression of the same proteins by the same methods as the instant claims (see below), said proteins would have the same immunological properties as those of the instant claims.

With regard to Point 3, contrary Applicant's assertion to the contrary, a given protein's immunological properties are inherent in nature. Moreover, Applicant is reminded that the instant claims are not limited to the production of antibodies with specificity for the protein, but encompass all immune responses.

With regard to Points 4-5, Goodman et al. specifically disclose the use of transgenic plants to express recombinant viral antigen proteins from leukemia and lymphotrophic retroviruses, herpes simplex virus, hepatitis B virus and adenovirus (see page 5, lines 1-3 and lines 21-26).

With regard to Points 6-7, the instant claims are drawn to methods of producing a vaccine (antigenic protein) utilizing transgenic plants, not methods of conferring immunity.

Consequently, Applicant's arguments are not germane. Moreover, it should be noted that the Service reference provided by Applicant was illegible and hence could not be fully considered.

As outlined previously, Goodman et al. disclose the use of transgenic plants to express recombinant viral antigen proteins from leukemia and lymphotrophic retroviruses, herpes simplex virus, hepatitis B virus and adenovirus (see page 5, lines 1-3 and lines 21-26). Goodman et al. further disclose the use of tomato plants, as well as other edible plants, to express said proteins (see page 8, lines 3-8). The methodology disclosed by Goodman et al. comprises: constructing a plasmid vector comprising the polynucleotide encoding the protein (viral antigen) coupled to a promoter that is functional in the plant host (see page 3, line 5 to page 7, line 4); transferring said plasmid vector to the plant cell (see page 7, lines 5-33); the regeneration of said plant from the transformed cells (see page 9, lines 15-21); the harvest of the plants or plant parts to obtain the expressed viral antigen protein (see page 9, lines 21-25); and the purification of said antigen protein (see page 9, lines 27-31). Consequently, Goodman et al. anticipate all the limitations of the rejected claims.

Claims 73-74 and 79 are rejected under 35 U.S.C. 102(e) as anticipated by Goodman et al. (U.S. Patent 4,956,282 – IDS-2) for the reasons set forth in the previous Office Action in the rejection of claims 73-74.

The instant claims are drawn to a method of producing a vaccine comprising constructing a plasmid vector or DNA fragment comprising a DNA sequence encoding a viral antigen

coupled to a plant functional promoter, transferring said vector or DNA fragment into a plant cell, regenerating a transgenic plant from said plant cell, obtaining the expressed viral antigen from a harvested portion of said transgenic plant and purifying said antigen. Said transgenic plant can be a tomato plant.

Applicant argues:

1. The amended claims recite the limitation "harvesting a portion of said regenerated transgenic plant, said portion containing said expressed immunogenic viral antigen, wherein said expressed antigen stimulates an immune response". Said limitation makes the instant claims distinguishable from the cited art since Goodman merely discloses that their proteins be "physiologically active".

2. Goodman discloses the production of primarily digestive enzymes that may or may not have immunogenic activity (column 1, lines 64-67).

3. Goodman fails to show their constructs induce systemic and mucosal antibody responses.

4. A protein antigen is not necessarily immunogenic unless an immunogenic region is present and accessible to the antibody-forming mechanism.

5. As illustrated by the reference by Service, the state of the art at the time of the Goodman reference was such that when an antigen in a plant was consumed by an animal it was unknown whether it would be digested or induce an immune response.

6. The art recognized problems associated with oral vaccines are not taken into account by Goodman.

7. The levels of expression disclosed in Goodman would not be high enough to achieve the response contemplated by the instant invention.

Applicant's arguments have been fully considered and deemed non-persuasive.

With regard to Point 1, since Goodman et al. disclose the expression of the same proteins by the same methods as the instant claims (see below), said proteins would have the same immunological properties as those of the instant claims.

With regard to Point 2, Goodman et al. specifically disclose the use of transgenic plants to express recombinant viral antigen proteins from leukemia and lymphotrophic retroviruses, herpes simplex virus, hepatitis B virus and adenovirus (see page 5, lines 1-3 and lines 21-26). Moreover, the portion of the reference cited by Applicant did not disclose that the expressed digestive proteins may or may not have immunogenic activity.

In response to applicant's argument that the references fail to show certain features of applicant's invention (Point 3), it is noted that the features upon which applicant relies (i.e., the vaccine induce systemic and mucosal antibody responses) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Applicant is reminded that the instant claims are not limited to the production of antibodies with specificity for the protein, but encompass all immune responses.

With regard to Points 5-7, the instant claims are drawn to methods of producing a vaccine (antigenic protein) utilizing transgenic plants, not methods of conferring immunity. Consequently, Applicant's arguments are not germane. Moreover, it should be noted that the Service reference provided by Applicant was illegible and hence could not be fully considered.

As outlined previously, Goodman et al. disclose the use of transgenic plants to express recombinant viral antigen proteins from leukemia and lymphotrophic retroviruses, herpes simplex virus, hepatitis B virus and adenovirus (see column 3, lines 30-35). Goodman et al. further disclose the use of tomato plants, as well as other edible plants, to express said proteins (see column 4, lines 58-62). The methodology disclosed by Goodman et al. comprises: constructing a plasmid vector comprising the polynucleotide encoding the protein (viral antigen) coupled to a promoter that is functional in the plant host (see column 2, line 10 to column 4, line 18); transferring said plasmid vector to the plant cell (see column 4, lines 19-48); the regeneration of said plant from the transformed cells (see column 5, lines 34-40; the harvest of the plants or plant parts to obtain the expressed viral antigen protein (see column 5, lines 39-42); and the purification of said antigen protein (see column 5, lines 46-50). Consequently, Goodman et al. anticipate all the limitations of the rejected claims.

35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The rejection of claim 75 under 35 U.S.C. 103(a) as being unpatentable over Goodman et al. (WO 87/00865 – IDS-2) is maintained for reasons of record.

The instant claims are drawn to a method of producing a vaccine comprising constructing a plasmid vector or DNA fragment comprising a DNA sequence encoding a viral antigen coupled to a plant functional promoter, transferring said vector or DNA fragment into a plant cell, regenerating a transgenic plant from said plant cell, obtaining the expressed viral antigen from a harvested portion of said transgenic plant and purifying said antigen. Said transgenic plant can be a tomato or a potato plant.

Applicant argues:

1. There is no suggestion in Goodman that it could be modified in the manner suggested by the Examiner.

2. Goodman discloses the production of primarily digestive enzymes that may or may not have immunogenic activity.

3. A protein antigen is not necessarily immunogenic unless an immunogenic region is present and accessible to the antibody-forming mechanism.

4. As illustrated by the reference by Service, the state of the art at the time of the Goodman reference was such that when an antigen in a plant is consumed by an animal it was unknown whether it would be digested or induce an immune response.

5. The art recognized problems associated with oral vaccines are not taken into account by Goodman.

6. The levels of expression disclosed in Goodman would not be high enough to achieve the response contemplated by the instant invention.

Applicant's arguments have been fully considered and deemed non-persuasive.

With regard to Point 1, since Goodman et al. disclose the use of tomato and tobacco plants to express said proteins (see page 8, lines 3-8) and tomato, potato and tobacco plants are all members of the same phylogenic family (*Solanaciai*), the use of potato plants merely constitutes an obvious variation of the method disclosed in the cited reference.

With regard to Points 2-3, since Goodman et al. disclose the expression of the same proteins by the same methods as the instant claims (see below), said proteins would have the same immunological properties as those of the instant claims. Goodman et al. specifically disclose the use of transgenic plants to express recombinant viral antigen proteins from leukemia and lymphotrophic retroviruses, herpes simplex virus, hepatitis B virus and adenovirus (see page 5, lines 1-3 and lines 21-26).

With regard to Points 4-6, the instant claims are drawn to methods of producing a vaccine (antigenic protein) utilizing transgenic plants, not methods of conferring immunity.

Consequently, Applicant's arguments are not germane. Moreover, it should be noted that the Service reference provided by Applicant was illegible and hence could not be fully considered.

As outlined previously, Goodman et al. disclose the use of transgenic plants to express recombinant viral antigen proteins from leukemia and lymphotrophic retroviruses, herpes simplex virus, hepatitis B virus and adenovirus (see page 5, lines 1-3 and lines 21-26). Goodman et al. further disclose the use of tomato plants, as well as other edible plants, to express said proteins (see page 8, lines 3-8). The methodology disclosed by Goodman et al. comprises: constructing a plasmid vector comprising the polynucleotide encoding the protein (viral antigen) coupled to a promoter that is functional in the plant host (see page 3, line 5 to page 7, line 4); transferring said plasmid vector to the plant cell (see page 7, lines 5-33); the regeneration of said plant from the transformed cells (see page 9, lines 15-21); the harvest of the plants or plant parts to obtain the expressed viral antigen protein (see page 9, lines 21-25); and the purification of said antigen protein (see page 9, lines 27-31). Goodman et al. differs from the claimed invention in that they do not explicitly disclose the use of potato plants as the recipients of the plasmid vector. However, since Goodman et al. disclose the use of tomato and tobacco plants to express said proteins (see page 8, lines 3-8) and tomato, potato and tobacco plants are all members of the same phylogenic family (*Solanaciai*), the use of potato plants merely constitutes an obvious variation of the method disclosed in the cited reference. One of skill in the art would have had a high expectation of success since potato plants are very similar to the disclosed tomato and tobacco plants. Moreover, Goodman et al. disclose that the recombinantly expressed protein could be found in plant parts such as tubers (see page 8, lines 9-11).

The rejection of claim 75 under 35 U.S.C. 103(a) being unpatentable over Goodman et al. (U.S. Patent 4,956,282 – IDS-2) is maintained for reasons of record.

The instant claims are drawn to a method of producing a vaccine comprising constructing a plasmid vector or DNA fragment comprising a DNA sequence encoding a viral antigen coupled to a plant functional promoter, transferring said vector or DNA fragment into a plant cell, regenerating a transgenic plant from said plant cell, obtaining the expressed viral antigen from a harvested portion of said transgenic plant and purifying said antigen. Said transgenic plant can be a tomato or a potato plant.

Applicant argues:

1. There is no suggestion in Goodman that it could be modified in the manner suggested by the Examiner.

2. Goodman discloses the production of primarily digestive enzymes that may or may not have immunogenic activity.

3. A protein antigen is not necessarily immunogenic unless an immunogenic region is present and accessible to the antibody-forming mechanism.

4. As illustrated by the reference by Service, the state of the art at the time of the Goodman reference was such that when an antigen in a plant was consumed by an animal it was unknown whether it would be digested or induce an immune response.

5. The art recognized problems associated with oral vaccines are not taken into account by Goodman.

6. The levels of expression disclosed in Goodman would not be high enough to achieve the response contemplated by the instant invention.

Applicant's arguments have been fully considered and deemed non-persuasive.

With regard to Point 1, since Goodman et al. disclose the use of tomato and tobacco plants to express said proteins (see page 8, lines 3-8) and tomato, potato and tobacco plants are all members of the same phylogenic family (*Solanaciai*), the use of potato plants merely constitutes an obvious variation of the method disclosed in the cited reference.

With regard to Points 2-3, since Goodman et al. disclose the expression of the same proteins by the same methods as the instant claims (see below), said proteins would have the same immunological properties as those of the instant claims. Goodman et al. specifically disclose the use of transgenic plants to express recombinant viral antigen proteins from leukemia and lymphotrophic retroviruses, herpes simplex virus, hepatitis B virus and adenovirus (see page 5, lines 1-3 and lines 21-26).

With regard to Points 4-6, the instant claims are drawn to methods of producing a vaccine (antigenic protein) utilizing transgenic plants, not methods of conferring immunity. Consequently, Applicant's arguments are not germane. Moreover, it should be noted that the Service reference provided by Applicant was illegible and hence could not be fully considered.

As outlined previously, Goodman et al. disclose the use of transgenic plants to express recombinant viral antigen proteins from leukemia and lymphotrophic retroviruses, herpes simplex virus, hepatitis B virus and adenovirus (see column 3, lines 30-35). Goodman et al. further disclose the use of tomato plants, as well as other edible plants, to express said proteins (see column 4, lines 58-62). The methodology disclosed by Goodman et al. comprises:

constructing a plasmid vector comprising the polynucleotide encoding the protein (viral antigen) coupled to a promoter that is functional in the plant host (see column 2, line 10 to column 4, line 18); transferring said plasmid vector to the plant cell (see column 4, lines 19-48); the regeneration of said plant from the transformed cells (see column 5, lines 34-40; the harvest of the plants or plant parts to obtain the expressed viral antigen protein (see column 5, lines 39-42); and the purification of said antigen protein (see column 5, lines 46-50). Goodman et al. differs from the claimed invention in that they do not explicitly disclose the use of potato plants as the recipients of the plasmid vector. However, since Goodman et al. disclose the use of tomato and tobacco plants to express said proteins (see column 4, lines 58-62) and tomato, potato and tobacco plants are all members of the same phylogenic family (*Solanaciai*), the use of potato plants merely constitutes an obvious variation of the method disclosed in the cited reference. One of skill in the art would have had a high expectation of success since potato plants are very similar to the disclosed tomato and tobacco plants. Moreover, Goodman et al. disclose that the recombinantly expressed protein could be found in plant parts such as tubers (see column 4, lines 60-62).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 73-75 and 79 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 73 is rendered vague and indefinite by the use of the phrase "wherein said expressed antigen stimulates an immune response". It is unclear what is meant by said phrase. How can an expressed antigen induce an immune response in a plant? Moreover, it is unclear what role the inducement of an immune response plays in the **production** of a recombinant protein (vaccine). As written, it is impossible to determine the metes and bounds of the claimed invention.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (571) 272-0866. The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

L. F. Smith

LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Robert A. Zeman
May 27, 2004